

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Peter J. Houzego, Peter N. Morgan, Peter H. Hirst, Duncan J. Westland and
Ian R. Wilding

Serial No.: 09/742,936

Art Unit: 3763

Filed: December 20, 2000

Examiner: Manuel A. Mendez

For: *AN INGESTIBLE DEVICE*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit a Supplemental Information Disclosure Statement, including one (1) page of Form PTO-1449. The Commissioner is hereby authorized to charge \$180.00, the fee required under 37 C.F.R. §1.17(p) for an Information Disclosure Statement filed after a notice of allowance under 37 C.F.R. §1.311, to Deposit Account No. 50-1868.

It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

Certification Under 37 C.F.R. §1.97 (e)(2)

No item of information contained in this Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, nor was it known to Applicants, more than three months prior to the filing of this Supplemental Information Disclosure Statement.

Publications

ERIKSEN, et al., "Equipment and methodology for relating gastrointestinal absorption to site of drug release," *J. Pharm. Sci.* 49: 151-156 (1960).

Remarks

Applicants have just become aware of the article cited above, a copy of which is enclosed. Eriksen, et al., discloses a capsule for release of drug at selected sites within the gastrointestinal tract (page 151, col. 1). Release of the drug is triggered when the subject swallowing the capsule is placed within a large induction heating coil (Figure 2). Drug is contained in a reservoir within the capsule. A spring-powered actuator pushes the drug out of the reservoir (page 152, col. 1). The spring is confined by wax, and then released by heating the capsule until the wax is melted (page 152). The wax is heated by exposure to radiofrequency waves that heat the capsule in the body to 50-52°C.

Independent claims 1, 3, 29, 33, 39, 42, 50 and 69, and claims dependent thereon, require features such as "a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range, the receiver including an air core having coiled therearound a wire" (claim 1); a "ferrite core having coiled therearound a

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT


wire for coupling received electromagnetic radiation to the releasable latch" (claim 3); "at a chosen time, generating at least one axial, oscillating magnetic field and directing the field at the abdomen of the mammal whereby the receiver intercepts the said field and triggers the latch to cause opening of the reservoir; and simultaneously inhibiting the generation of long wave radio waves and short wave electrostatic radiation in the vicinity of the said abdomen" (claim 29); "a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device," (claims 33 and 106); "characterised in that the spring, in its uncompressed state, has a minimum helical angle of 15°" (claims 39 and 104); "the energy source including a compressed spring capable of acting on the actuator mechanism the expansion of which is initiatable by the latch and the work of the expansion of which causes operation of the actuator mechanism, characterised in that the spring includes a pair of wires each coiled in loops to define a pair of hollow cylinder-like shapes, a first said cylinder-like shape being of a greater internal diameter than the outer diameter of the second said cylinder-like shape and the first cylinder-like shape encircling the second cylinder" (claims 42 and 105); "the energy source including a compressed spring the expansion of which is initiatable by the latch and the work of the expansion of which causes operation of the actuator mechanism, characterised in that the spring comprises a stack of resiliently deformable discs, the periphery of each disc having formed therein a series of waves, the waves of respective said discs connecting such that the peak of each wave contacts the trough of a wave of an adjacent said disc" (claim 50); "the device includes a heater for heating the latch whereby, on the receiver-detecting the said radiation the receiver operates to power the heater and thereby release the latch, permitting expulsion of the substance from the reservoir" (claim 69).

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

None of these features are disclosed by, nor obvious over, Eriksen, since there is no teaching or suggestion to use any other means for releasing drug, or any interactive feature.

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,


Patrea L. Pabst
Reg. No. 31,284

Dated: July 16, 2003
HOLLAND & KNIGHT LLP
One Atlantic Center
1201 West Peachtree Street, N.E.
Suite 2000
Atlanta, Georgia 30309-3400
404-817-8473
FAX 404-817-8588
www.hklaw.com

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

Appendix. Clean Version of Amended Claims as Allowed

1. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range, the receiver including an air core having coiled therearound a wire; characterised in that the coiled wire lies on or is embedded in an outer wall of the device.

2. A device according to Claim 1 wherein the diameter of the coils of the wire is in the range 8-12mm and its length is in the range 10-20mm.

3. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

radiation within a predetermined characteristic range, the device including a ferrite core having coiled therearound a wire for coupling received electromagnetic radiation to the releasable latch, characterised in that the device comprises an elongate, hollow housing, the ferrite core being elongate with its longitudinal axis aligned with the longitudinal axis of the hollow housing.

4. A device according to Claim 1, wherein the receiver includes the said ferrite core and coil.

5. A device according to Claim 3, wherein the receiver includes the said ferrite core and coil.

6. A device according to Claim 1, wherein the air core and coil are spaced from any fluid within or outside the device by a distance of 0.1mm to 1mm.

7. A device according to Claim 3, wherein the ferrite core and coil are spaced from any fluid within or outside the device by a distance of 0.1mm to 1mm.

8. A device according to Claim 1, including a transmitter having an air or ferrite core having coiled therearound a wire for transmitting electromagnetic radiation.

9. A device according to Claim 3, including a transmitter having an air or ferrite core having coiled therearound a wire for transmitting electromagnetic radiation.

29. A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, causing a mammal to ingest an ingestible device comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; the receiver being capable of extracting energy from an oscillating magnetic field and the method comprising:

at a chosen time, generating at least one axial, oscillating magnetic field and directing the field at the abdomen of the mammal whereby the receiver intercepts the said field and triggers the latch to cause opening of the reservoir; and

simultaneously inhibiting the generation of long wave radio waves and short wave electrostatic radiation in the vicinity of the said abdomen.

30. A method according to Claim 29 including the step of generating two or more axial, oscillating magnetic fields whose axes are mutually skewed.

31. A method according to Claim 29 including the step of generating two or more axial, oscillating magnetic fields whose axes are mutually skewed and including the step of generating three said fields, wherein the axes of the said fields are mutually orthogonal.

32. A method according to Claim 29 wherein the or each said field is generated using a coil pair operatively connected to a source of an oscillating current.

33. (amended) An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source;

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and

a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device,

the said reservoir including an exit aperture, for the substance, closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism; wherein:

- (i) the latch is thermally actuated;
- (ii) the energy source is held in a potential energy state until the latch operates; and
- (iii) the device includes a heater for heating the latch whereby, on the receiver detecting the said radiation the receiver operates to power the heater and thereby release the latch, permitting expulsion of the substance from the reservoir; characterised in that:

the device also includes a restraint operable to limit operation of the actuator mechanism; and in that, on release of the latch, the restraint operates a switch to activate the transmitter for transmission of a said signal.

34. A device according to Claim 33 wherein:

the actuator mechanism includes a moveable member moveable under power of kinetic energy from the energy source to promote expulsion of the substance from the reservoir;

the restraint includes a flexible member interconnecting the moveable member and an anchorage fixed relative to the remainder of the device; and

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

the switch includes a breakable, electrically conductive member, the flexible member and the breakable member being mutually engageable whereby on movement of the moveable member sufficiently partly or completely to expel or initiate expulsion of the substance from the reservoir the flexible member engages and breaks the breakable member to operate the switch.

35. A device according to Claim 33 wherein the actuator mechanism includes a piston moveable under power from the energy source for compressing the substance in the reservoir to promote its expulsion therefrom.

36. A device according to Claim 33 wherein the transmitter includes a resonant circuit connectable to draw power from the receiver; and the breakable member is an electrical short that electrically isolates the resonant circuit from the receiver until the flexible member breaks the breakable member.

37. A device according to Claim 33 wherein the length of the flexible member is such as to limit the travel of the moveable member to a chosen maximum.

38. A device according to Claim 33 wherein the restraint and the switch are so dimensioned and/or located that the restraint operates the switch at a time corresponding to a predetermined amount of movement of the moveable member.

39. (amended) An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

- an openable reservoir, for the substance, that is sealable against leakage of the substance;
- an actuator mechanism for opening the reservoir;
- an energy source, operatively connected for powering the actuator mechanism;
- a releasable latch for controllably switching the application of power to the actuator from

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range;

the energy source including a compressed spring capable of acting on the actuator mechanism the expansion of which is initiatable by the latch and the work of the expansion of which causes operation of the actuator mechanism, characterised in that the spring, in its uncompressed state, has a minimum helical angle of 15°.

40. A device according to Claim 39 wherein the spring includes a wire whose diameter is approximately 0.8mm.

41. A device according to Claim 39 wherein the spring defines a hollow cylinder.

42. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range;

the energy source including a compressed spring capable of acting on the actuator mechanism the expansion of which is initiatable by the latch and the work of the expansion of which causes operation of the actuator mechanism, characterised in that the spring includes a

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

pair of wires each coiled in loops to define a pair of hollow cylinder-like shapes, a first said cylinder-like shape being of a greater internal diameter than the outer diameter of the second said cylinder-like shape and the first cylinder-like shape encircling the second cylinder.

43. A device according to Claim 42 wherein the wire of the first cylinder-like shape is looped in a clockwise direction and the wire of the second cylinder-like shape is looped in an anticlockwise direction; or *vice versa*.

44. A device according to Claim 43 wherein the wires of the first and second cylinder-like shapes are wound in the same direction.

45. A device according to Claims 42 wherein the first and second cylinder-like shapes are spaced from one another in the radial direction of the spring cross section.

46. A device according to Claim 42 wherein at least one of the wires includes a coating of an insulator over at least part of its length, whereby to insulate it from the other said wire.

47. A device according to Claim 42 wherein the ends of the wires defining each said wire are flush with the adjacent loops thereof.

48. A device according to Claim 42 wherein the compressed length of the spring is approximately $\frac{1}{3}$ of its length in the uncompressed condition.

49. A device according to Claim 42 wherein the force applied by the spring to the actuator mechanism exceeds the maximum resistive force resisting operation of the actuator, at the time when the maximum resistive force applies.

50. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

an openable reservoir, for the substance, that is sealable against leakage of the substance;
an actuator mechanism for opening the reservoir;
an energy source, operatively connected for powering the actuator mechanism;
a releasable latch for controllably switching the application of power to the actuator from the energy source; and

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range;

the energy source including a compressed spring the expansion of which is initiatable by the latch and the work of the expansion of which causes operation of the actuator mechanism, characterised in that the spring comprises a stack of resiliently deformable discs, the periphery of each disc having formed therein a series of waves, the waves of respective said discs connecting such that the peak of each wave contacts the trough of a wave of an adjacent said disc.

51. A device according to Claim 50 wherein the waves of each disc radiate generally from its centre.

52. A device according to Claim 50 wherein each disc is an annulus.

53. A device according to Claim 50 wherein each disc is an annulus and wherein each annulus is about 0.25mm thick and has three said waves, the peak to trough distance of the waves being about 2mm.

54. A device according to Claim 50 wherein each disc is an annulus and wherein the spring includes 16 said annuli secured together at the respective peaks and troughs of the waves.

55. A device according to Claim 50 wherein each disc is an annulus and wherein the outer diameter of each annulus is about 8.5mm and the inner diameter is about 4.5mm.

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

56. (amended) A device according to Claim 39 wherein the actuator mechanism includes a piston moveable under power from the spring for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member fixed relative to the remainder of the device.

the device.

57. A device according to Claim 56 wherein the spring encircles one or more further components of the device.

58. A device according to Claim 1 including a retainer for retaining moveable components within the device.

59. A device according to Claim 3 including a retainer for retaining moveable components within the device.

60. A device according to Claim 29 including a retainer for retaining moveable components within the device.

61. A device according to Claim 33 including a retainer for retaining moveable components within the device.

62. A device according to Claim 39 including a retainer for retaining moveable components within the device.

63. A device according to Claim 42 including a retainer for retaining moveable components within the device.

64. A device according to Claim 50 including a retainer for retaining moveable components within the device.

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

65. (amended) A device according to Claim 59 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

66. A device according to Claim 56 wherein the piston includes a flexible annular lip for slidably sealingly engaging the interior of the reservoir.

67. A device according to Claim 56 wherein the piston includes a flexible annular lip for slidably sealingly engaging the interior of the reservoir and wherein the cross section of the lip tapers towards its free edge.

68. A device according to Claim 56 wherein the piston includes a flexible annular lip for slidably sealingly engaging the interior of the reservoir and wherein the cross section of the lip is generally parallel sided.

69. An ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, comprising:

an openable reservoir, for the substance, that is sealable against leakage of the substance;

an actuator mechanism for opening the reservoir;

an energy source, operatively connected for powering the actuator mechanism;

a releasable latch for controllably switching the application of power to the actuator from the energy source;

a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and

a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device;

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

the said reservoir including an exit aperture, for the substance, closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism; wherein

- (i) the latch is thermally actuated;
- (ii) the energy source is held in a potential energy state by the latch until the latch operates; and
- (iii) the device includes a heater for heating the latch whereby, on the receiver-detecting the said radiation the receiver operates to power the heater and thereby release the latch, permitting expulsion of the substance from the reservoir; characterised in that the device also includes
 - (a) a restraint operable to limit operation of the actuator mechanism;
 - (b) a switch for switchably operating the transmitter; and
 - (c) a switch member operatively interconnecting the actuator mechanism and the switch such that operation of the actuator mechanism causes the switch member to operate the said switch.

70. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the moveable member moves before the switch member operates the switch.

71. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the moveable member moves before the switch member operates the switch and wherein the switch member interconnects the moveable member and the switch; and includes a slack, flexible

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

member the slackness of which provides the said lost motion arrangement.

72. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the moveable member moves before the switch member operates the switch and wherein the switch member interconnects the moveable member and the switch; and includes a slack, flexible member the slackness of which provides the said lost motion arrangement, the device including a pcb having a breakable wire secured at spaced locations thereon to define the switch, the pcb being perforated and the said switch and the said moveable member lying respectively at opposite sides of the pcb; and the switch member including a slack, flexible filament that passes through a perforation in the pcb and including a loop that encloses the breakable wire, the filament being secured to the moveable member whereby when the moveable member moves the filament tightens such that the loop breaks the breakable wire.

73. A device according to Claim 69 including a pcb supporting the receiver and the transmitter, the receiver and the transmitter each including a resistor track secured on the pcb, the resistor tracks of the transmitter and receiver lying respectively on opposite sides of the pcb.

74. A device according to Claim 69 including a pcb supporting the receiver and the transmitter, the receiver and the transmitter each including a resistor track secured on the pcb, the resistor tracks of the transmitter and receiver lying respectively on opposite sides of the pcb and wherein the pcb includes one or more perforations in the vicinity of each said resistor track.

75. A device according to Claim 69 wherein the actuator mechanism includes a moveable member and the switch member includes a lost motion arrangement whereby the moveable member moves before the switch member operates the switch and wherein the switch

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

member interconnects the moveable member and the switch; and includes a slack, flexible member the slackness of which provides the said lost motion arrangement, the device including a pcb having a breakable wire secured at spaced locations thereon to define the switch, the pcb being perforated and the said switch and the said moveable member lying respectively at opposite sides of the pcb; and the switch member including a slack, flexible filament that passes through a perforation in the pcb and including a loop that encloses the breakable wire, the filament being secured to the moveable member whereby when the moveable member moves the filament tightens such that the loop breaks the breakable wire; wherein a projection protrudes from an edge of a perforation through the pcb; and wherein the latch includes a sharp melting point filament interconnecting the actuator member and the said projection.

76. A device according to Claim 75 wherein the heater is secured to the projection in heat transmitting proximity to the sharp melting point filament.

77. (amended) A device according to Claim 1, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

78. (amended) A device according to Claim 1, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

79. A method according to Claim 29, including the step of indicating the location of the device in the GI tract of the mammal, using a radioisotope tag.

80. A method according to Claim 29, including the step of indicating the location of the device in the GI tract of the mammal, using a radioisotope tag and wherein the step of indicating the location includes using Gamma scintigraphy to indicate the location of the device

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

in the said GI tract.

81. (new) A method according to Claim 29, wherein the energy source includes an initially compressed, helical spring that is capable of acting on the actuator mechanism; the expansion of which is initiatable by the latch; and the work of the expansion of which causes operation of the actuator mechanism, the spring having, in its uncompressed state, a minimum helical angle of 15°.

82. (new) A method according to Claim 81 wherein the spring includes a wire whose diameter is approximately 0.8 mm.

83. (new) A method according to Claim 81 wherein the spring defines a hollow cylinder.

84. (new) A method according to Claim 29 wherein the energy source includes an initially compressed spring that is capable of acting on the actuator mechanism; the expansion of which is initiatable by the latch; and the work of the expansion of which causes operation of the actuator mechanism, the spring including a pair of wires each coiled in loops to define a pair of cylinder-like shapes, a first said cylinder-like shape being of a greater internal diameter than the outer diameter of the second said cylinder-like shape and the first cylinder-like shape encircling the second cylinder.

85. (new) A method according to Claim 84 wherein the wire of the first cylinder-like shape is looped in a clockwise direction and the wire of the second cylinder-like shape is looped in an anticlockwise direction; or *vice versa*.

86. (new) A method according to Claim 84 wherein the wires of the first and second cylinder-like shapes are wound in the same direction.

U.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

87. (new) A method according to Claim 84 wherein the first and second cylinder-like shapes are spaced from one another in the radial direction of the spring cross-section.

88. (new) A method according to Claim 84 wherein the at least one of the wires includes a coating of an insulator over at least part of its length, whereby to insulate it from the other said wire.

89. (new) A method according to Claim 84 wherein the ends of the wires defining each said cylinder-like shape are flush with the adjacent loops thereof.

90. (new) A method according to Claim 84 wherein the compressed length of the spring is approximately one-third of its length in the uncompressed condition.

91. (new) A method according to Claim 84 wherein the force applied by the spring to the actuator mechanism exceeds the maximum resistive force resisting operation of the actuator, at the time when the maximum resistive force applies.

92. (new) A method according to Claim 29, wherein the energy source includes an initially compressed spring that is capable of acting on the actuator mechanism; the expansion of which is initiatable by the latch; and the work of the expansion of which causes operation of the actuator mechanism, the spring including a stack of resiliently deformable discs, the periphery of each disc having formed therein a series of waves, the waves of respective said discs connecting such that the peak of each wave contacts the trough of a wave of an adjacent said disc.

93. (new) A method according to Claim 92 wherein the waves of each disc radiate generally from its centre.

94. (new) A method according to Claim 92 wherein each disc is an annulus.

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

95. (new) A method according to Claim 92 wherein each disc is an annulus and each annulus is about .25 mm thick and has three said waves, the peak to trough distance of the waves being about 2mm.

96. (new) A method according to Claim 92 wherein each disc is an annulus and the spring includes sixteen said annuli secured together at the respective peaks and troughs of the waves.

97. (new) A method according to Claim 92 wherein each disc is an annulus the outer diameter of which is about 8.5 mm and the inner diameter of which is about 4.5 mm.

98. (new) A method according to Claim 81 wherein the actuator mechanism includes a piston that is moveable, under power from the spring, for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member that is fixed relative to the remainder of the device.

99. (new) A method according to Claim 84 wherein the actuator mechanism includes a piston that is moveable, under power from the spring, for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member that is fixed relative to the remainder of the device.

100. (new) A method according to Claim 92 wherein the actuator mechanism includes a piston that is moveable, under power from the spring, for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

indirectly with the piston and secured at its other end to a member that is fixed relative to the remainder of the device.

101. (new) A method according to Claim 98 wherein the spring, in use, encircles one or more further components of the device.

102. (new) A method according to Claim 99 wherein the spring, in use, encircles one or more further components of the device.

103. (new) A method according to Claim 100 wherein the spring, in use, encircles one or more further components of the device.

104. (new) A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, the device including an openable reservoir, for the substance, that is sealable against leakage of the substance; an actuator mechanism for opening the reservoir; an energy source that is operatively connected for powering the actuator mechanism; a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source; a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device, the said reservoir including an exit aperture, for the substance, that is initially closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism, the method comprising the steps of charging the reservoir with a said substance; setting the latch; causing ingestion of the device by a human or animal; and causing the receiver to detect electromagnetic radiation in the predetermined characteristic range, thereby causing expulsion of the substance from the reservoir

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

via the exit aperture, the method including the steps of causing expansion from an initial, compressed state a helical spring defining the said energy source and having, in its uncompressed state, a minimum helical angle of 15°.

105. (new) A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, the device including an openable reservoir, for the substance, that is sealable against leakage of the substance; an actuator mechanism for opening the reservoir; an energy source that is operatively connected for powering the actuator mechanism; a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source; a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device, the said reservoir including an exit aperture, for the substance, that is initially closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism, the method comprising the steps of charging the reservoir with a said substance; setting the latch; causing ingestion of the device by a human or animal; and causing the receiver to detect electromagnetic radiation in the predetermined characteristic range, thereby causing expulsion of the substance from the reservoir via the exit aperture, the method including the steps of causing expansion from an initial, compressed state a spring, that defines the said energy source, including a pair of wires each coiled in loops to define a pair of cylinder-like shapes, a first said cylinder-like shape being of a greater internal diameter than the outer diameter of the second said cylinder-like shape and the first cylinder-like shape encircling the second cylinder.

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

106. (new) A method of operating an ingestible device for delivering a substance to a chosen or identifiable location in the alimentary canal of a human or animal, the device including an openable reservoir, for the substance, that is sealable against leakage of the substance; an actuator mechanism for opening the reservoir; an energy source that is operatively connected for powering the actuator mechanism; a releasable latch for controllably switching the application of power to the actuator mechanism from the energy source; a receiver of electromagnetic radiation, for operating the latch when the receiver detects radiation within a predetermined characteristic range; and a transmitter of electromagnetic radiation for transmitting a signal indicative of operation of the device, the said reservoir including an exit aperture, for the substance, that is initially closed by a closure member that is sealingly retained relative to the aperture, the exit aperture being openable on operation of the actuator mechanism, the method comprising the steps of charging the reservoir with a said substance; setting the latch; causing ingestion of the device by a human or animal; and causing the receiver to detect electromagnetic radiation in the predetermined characteristic range, thereby causing expulsion of the substance from the reservoir via the exit aperture, the method including the steps of causing expansion from an initial, compressed state a spring, that defines the said energy source, including a stack of resiliently deformable discs, the periphery of each disc having formed therein a series of waves, the waves of respective said discs connecting such that the peak of each wave contacts the trough of a wave of an adjacent said disc.

107. (new) A device according to Claim 42 wherein the actuator mechanism includes a piston moveable under power from the spring for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

the piston and secured at its other end to a member fixed relative to the remainder of the device.

108. (new) A device according to Claim 50 wherein the actuator mechanism includes a piston moveable under power from the spring for compressing the substance in the reservoir to promote its expulsion therefrom, the spring being engaged at one end directly or indirectly with the piston and secured at its other end to a member fixed relative to the remainder of the device.

109. (new) A device according to Claim 103 wherein the spring encircles one or more further components of the device.

110. (new) A device according to Claim 104 wherein the spring encircles one or more further components of the device.

111. (new) A device according to Claim 60 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

112. (new) A device according to Claim 61 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

113. (new) A device according to Claim 62 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

114. (new) A device according to Claim 63 wherein the retainer includes a rib that reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

115. (new) A device according to Claim 64 wherein the retainer includes a rib that

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

reduces the cross sectional area of the hollow interior of the device in the vicinity of an opening therein.

116. (new) A device according to Claim 103 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir.

117. (new) A device according to Claim 104 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir.

118. (new) A device according to Claim 103 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip tapers towards its free edge.

119. (new) A device according to Claim 104 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip tapers towards its free edge.

120. (new). A device according to Claim 103 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip is generally parallel sided.

121. (new) A device according to Claim 104 wherein the piston includes a flexible annular lip for slidingly sealingly engaging the interior of the reservoir and wherein the cross section of the lip is generally parallel sided.

122. (new) A device according to Claim 3, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

123. (new) A device according to Claim 29, the reservoir of which includes a charge of

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

124. (new) A device according to Claim 33, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

125. (new) A device according to Claim 39, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

126. (new) A device according to Claim 42, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

127. (new) A device according to Claim 50, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

128. (new) A device according to Claim 69, the reservoir of which includes a charge of liquid, powdered or solid substance or a suspension or solution for discharge into the GI tract of a mammal.

129. (new) A device according to Claim 3, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

130. (new) A device according to Claim 29, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

131. (new) A device according to Claim 33, including a radioisotope tag generating

U.S.S.N.: 09/742,936
Filed: December 20, 2000
SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

132. (new) A device according to Claim 39, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

133. (new) A device according to Claim 42, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

134. (new) A device according to Claim 50, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

135. (new) A device according to Claim 69, including a radioisotope tag generating radiation that is detectable for indicating the location of the device in the GI tract of a mammal.

ATL1 #585313 v1

